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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,446	12/05/2003	Scott A. Burton	59427US002	9352

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.		Applicant(s)	
	10/728,446		BURTON ET AL.	
	Examiner		Art Unit	
	Isis A. Ghali		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/08/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 15-24, 26-35, 38-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 25, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3).

Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :
05/27/05; 06/13/05; 01/30/06; 020/6/06; 01/08/07; 01/08/07; 05/08/07; 06/5/07.

DETAILED ACTION

The receipt is acknowledged of applicants IDS filed 05/25/2005; IDS filed 06/13/2005; IDS filed 01/30/2006; IDS filed 02/06/2006; two IDSs filed 01/08/2007; IDS filed 05/08/2007; IDS filed 06/05/2007; and election filed 05/08/2007.

Claims 1-44 are pending.

Response to Election/Restrictions

1. The species election within Group I regarding (a) addition of the oxidizing agent, (b) silver-containing compound, (c) ammonium-containing compound, and (d) substrate, has been withdrawn.
2. Applicant's election with traverse of Group I, claims 1-14, 25, 36 and 37 in the reply filed on 05/08/2007 is acknowledged. The traversal is on the ground(s) that claim 1 is generic for claims 15 and 27, and all the inventions can be evaluated in one search without burden on the examiner. This is not found persuasive because invention II is distinct from inventions I and III because it specifically requires silver oxide and ammonium carbonate that not required by inventions claim 1 and ammonium carbonate is not required by claim 27. Invention I requires silver containing compound and ammonium containing compound, while, Invention III requires silver oxide and does not

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require specific ammonium containing compound and further requires adding oxidizing agent. Therefore, the prior art that anticipates claim 1 may not anticipate claims 15 and 27. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

3. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between Group IV and the other Groups I-III, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 15-24, 26-35, 38, 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I-III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/08/2007.

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5. Claims 40-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group IV, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/08/2007.

Claims 1-14, 25, 36 and 37 are included in the prosecution.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 of copending Application No. 10/917,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in

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the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: method of coating silver compound on a substrate comprising combining silver-containing compound with ammonium-containing compound in a solution, coating the solution on a substrate and drying the substrate. The present claims anticipate the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

8. The attempt to incorporate subject matter into this application by reference to copending applications to describe medical articles, pages 6-8, is ineffective because the applications serial numbers are left blank.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claim 1 is drawn to "method of coating silver on a substrate". Claim 10 recites that silver containing compound remains on the substrate after drying. Claim 25 requires the article made by the method of claim 1 is essentially free of the ammonium compound or residual components of the ammonium compound and the silver-containing compound introduced during the application of the solution. It is not clear from the disclosure, as well as claim 25 if the article coated by the coating solution will have silver compound or not?

In page 1 of the present specification, applicants disclosed that:

"The present invention is directed to a method of coating silver compounds on a medical article, such as a gauze, a nonwoven, a foam, and a hydrocolloid."

More support for silver compound coated on a substrate is in page 2, lines 6-9 where applicant stated that:

"The silver oxide is essentially the only compound that remains on the substrate after drying the substrate, with essentially all of the ammonium-containing compound removed after drying the substrate."

In page 3, line 25 till page 4, line 6, applicants disclosed that:

"Once dried, the substrate remains coated with the silver compound. The coated substrates are essentially free of silver metal, i.e., Ag(0). In some embodiments, the choice of starting materials results in a coating that leaves no residue with essentially only the silver compound remaining on the substrate, and all other components of the silver solution removed from the substrate upon drying. Preferably, the silver solution is formed from the combination of silver oxide and ammonium carbonate. After coating, ammonia and carbon dioxide are driven off, leaving only the silver oxide remaining on the substrate."

Additionally, applicants disclosed in page 4, lines 25-31, that the silver compositions once coated, are stable under different conditions.

Therefore, the invention requires and directed to silver compounds coated on substrate, and further stable on the substrate. All the examples show substrate coated with silver containing compound.

However, claim 25 requires article essentially free of the silver compounds. The same is described in page 2, lines 12-14. Nowhere applicants disclosed such an article or substrate that essentially free of silver compounds or even a desire to obtain it. No examples or description made for article or substrate essentially free of silver containing compounds. The present invention is aiming at providing coating on a substrate of silver containing compounds to provide antimicrobial effect, and it is not clear from the disclosure how and why a substrate free of such a coating will be produced. It is not also clear from the disclosure why the silver compounds are coated on the substrate and then are removed? What benefit is provided to the substrate if the coated material is completely removed to provide substrate free from coating?

The disclosure of coating essentially free of silver containing compounds without partial or complete description of such coating does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The disclosure

does not meet the written description requirement for coating essentially free of silver containing compounds. One skilled in the art could not recognize or understand coating essentially free of silver containing compounds from description and examples showing substrates coated with silver containing compounds having antimicrobial effects. The disclosure does not provide such an article, and method of its production, where a coating free of silver containing compounds is desired and still having antimicrobial effect, without antimicrobial agent. The disclosure neither provides such an article nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The disclosure represents only an invitation to experiment regarding possible complete removal of the coating and its benefit and effects as medical article essentially free of antimicrobial silver.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. The invention is, for purpose of the "written description" inquiry, what ever is now claimed. The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed. One cannot describe what one has not conceived.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 14 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, the claim recites the broad limitation "film", and also recites the narrower limitations "gauze" and "foam".

Regarding claim 25, the expression "essentially free" does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2, 5, 9-14, 25 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 769,799 ('799).

GB '799 disclosed method for coating substrate of fabric or fibers with sparingly water soluble silver salt including dipping or wetting the substrate surface with solution comprising aqueous solution of silver salt including silver nitrate, and ammonia compound to solubilize the silver salt, followed by drying the wet substrate (page 1,

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lines 81-85; page 2, lines 1-5, 18-26, 30-36, 112-120; page 3, lines 112-115; the tale in page 6). The coating solution further comprises stabilizer that reads on antioxidant claimed by claims 12 and 13, and the stabilizer is added to the coating solution that is applied to the substrate, therefore, the limitations of claims 12 and 13 are met. Drying by heat will inherently remove volatile components of the coated solution and silver will remain. GB '799 disclosed that the solution can be coated on medical articles surgical masks and surgeons hats (page 5, lines 123-125). The pH of the coating solution comprising the same ingredients including ammonia will inherently have the same alkaline pH value. The coated substrate is lethal to bacteria and fungi falling on its surface and remains this way for long time (page 2, lines 3-5). GB '799 disclosed that dipping the substrate in the solution is carried out at temperature 60 °C 80 °C, however, temperature variation does not produce any significant change in the treated article, and even higher temperature caused color changes (page 6, lines 10-20).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3, 4, 7, 8 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '799 in view of WO 02/43743 ('743).

The teachings of GB '799 are discussed under 102 rejection as set forth in this office action.

Although GB '799 disclosed insignificant effect of temperature variation of the dipping solution on the treated article and the disadvantage of higher temperature, however GB '799 does not teach specifically temperature less than 40 °C as claimed by claims 3 and 4.

Further GB '799 disclosed ammonia added to the sparingly water soluble salt solution for solubilizing the solution, however, it does not explicitly teach ammonium salts claimed by claims 7 and 8.

Although GB '799 teaches coating medical articles with the disclosed solution, however, the reference does not explicitly teach coating wound dressing.

WO '743 teaches wound dressing made of polymer such as hydrocolloid or polymer fibers prepared by method comprising the steps of subjecting the polymer to

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aqueous solution comprising silver salts such as nitrate, and ammonium salt such as acetate or carbonate at ambient temperature, i.e. below 40 °C, and drying the material (page 3, lines 24-30; page 4, lines 1-15; page 5, lines 3, 10-15; page 7, lines 1-3, 12-15, claim 9). The produced material is stable (page 8, line 3). The ammonium salts facilitate the silver photostabilization (page 7, lines 4-7). The solution further comprises peroxide as stabilizing agent (page 7, lines 4-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article as disclosed by GB '799, and dry the article at ambient temperature as disclosed by WO '734 because WO '743 although taught range of temperature up to 100 °C, however preferred ambient temperature, and also because GB '799 taught that temperature variations does not have significant effect of the treated article and taught that high temperature is disadvantageous, with reasonable expectation of having method to successfully coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article at ambient temperature with less cost and avoidance of deleterious heat effects.

It would have been also obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article as disclosed by GB '799, and replace the ammonia

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compound with ammonium carbonate as disclosed by WO '743, motivated by the teaching of WO '743 that ammonium salts including ammonium carbonate facilitates photostabilization of silver, with reasonable expectation of having method to coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonium carbonate on the article followed by drying the article wherein the coating over the article is photostable.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article as disclosed by GB '799, and use such a coating to coat wound dressing as disclosed by US WO '743, motivated by the teaching of GB '799 that article coated with such a coating is lethal to bacteria and fungi falling on its surface and remains this way for long time, and also motivated by the teaching of WO '743 that wound dressing subjected to solution comprising silver salt and ammonium salts is photostable, with reasonable expectation of having method to coat a wound dressing with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonium carbonate on the article followed by drying the article wherein the coating over the dressing is lethal to the microorganisms that come in contact of the surface of the dressing and also photostable.

19. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB '799 in view of US 4,592,920 ('920).

The teachings of GB '799 are discussed under 102 rejection as set forth in this office action.

Although GB '799 disclosed sparingly water soluble silver salts, however, the reference does not explicitly teach silver oxide.

US '920 teaches coating of medical devices with coat containing antimicrobial metal that is biocompatible with body including silver oxide (abstract; col.2, lines 1-3; col.3, lines 22-25, 32-33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound by coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article as disclosed by GB '799, and replace the water sparingly silver salt with silver oxide disclosed by US '920, motivated by the teaching of US '920 that silver oxide is an antimicrobial silver salt suitable to be coated on medical devices because it is biocompatible with body, with reasonable expectation of having method to coat a medical article with silver compound by coating an aqueous solution comprising silver oxide and ammonia compound on the article followed by drying the article wherein the coating is safe and biocompatible with the body.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615



IG

ISIS GHALI
PRIMARY EXAMINER